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Application and validation of a statistically derived risk-based sampling plan to improve efficiency of inspection and enforcement

Kyung-Min Lee [a,*], Timothy J. Herrman [a], Susie Y. Dai [a,b]

[a] Office of the Texas State Chemist, Texas A&M AgriLife Research, Texas A&M University System, College Station, TX 77841, USA
[b] Department of Veterinary Pathobiology, College of Veterinary Medicine & Biomedical Sciences, Texas A&M University, College Station, TX 77843, USA

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ABSTRACT

The statistically derived risk-based sampling plan for surveillance sample assignments of chemical and biological hazards was designed using binomial probability distribution. The binomial statistics was applied to the past 3-year data to estimate a confidence interval and a sample size aiming to improve efficiency and effectiveness of the agency's sampling and inspectional activities. The accuracy of the statistical models and computed estimates were validated in the following years. The ranges of confidence interval and sample size appeared to be significantly influenced by a level of the violation rate of feed product samples, an acceptable error, a number of the analyzed samples, and a statistical significance level. The violation rates of feed products for target analytes (aflatoxins, fumonisins, *Salmonella*, and dioxin) in the validation data were lower than those of the average 3-year data in most feed products. Besides, the actual violation rates of the validation samples did not exactly fall within the anticipated range of the confidence interval estimates. Such a discrepancy is considered introduced by several factors such as sample size adequacy, skewed distribution of a target analyte in feed products, and unique analyte/product combination. The overall study results indicate that the risk-based plan of work would provide a more effective and efficient risk management tool to help improve the oversight of the feed industry and the compliance to feed safety standards.

1. Introduction

The global regulatory and enforcement community has consistently adopted scientific risk analysis approaches. Following this trend, regulatory agencies have developed their plan of work for establishing and addressing priorities. The Texas State Chemist (OTSC) in charge of the feed and fertilizer regulations as defined by the Texas Agricultural Code has created a statistically derived risk-based plan of work by incorporating several innovative concepts to improve the regulatory oversight of the Texas feed industry through improved efficiency and effectiveness of sampling and inspectional activities. The OTSC plan of work includes sampling of feed for nutritional properties and biological and chemical hazards such as *Salmonella*, *E. coli*, heavy metals, mycotoxins, dioxins, and drug residues. According to this plan of work, sampling and inspection are carried out more intensively on firms with a record of high violations (Lee, Herrman, & Jones, 2009).

Monitoring feed firms through sampling activities is a fundamental part of regulatory compliance and inspection programs. Sampling feed products including feed grains, feed ingredients, and finished feeds related to food safety activities is no different than sampling food and food-related products in general. Accurate estimation of the attribute of feed product population through sampling is not an easy task in Texas because all feed products which are manufactured and distributed in the state reach approx. 19 million tons by more than 4000 facilities and guarantors. The results obtained from random samples taken from the feed product population provide an estimate of the population attribute. Accurate estimates of the attribute of feed product population can provide more effective regulatory and compliance options for risk management. Therefore, a discerning sampling knowledge and understanding of the parameters of the statistical distribution of the population attribute are critical to choose an adequate sampling method, sampling strategy, and sample size (Hellevang, Backer, & Maher, 1992; Minkkinen, 2004). A specific sampling plan to accurately represent the population attribute should carefully consider all critical points including a sufficient sample size, choice of the

* Corresponding author.
E-mail address: kml@otsc.tamu.edu (K.-M. Lee).

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sampling points/devices, frequency of sampling, and distribution of sample components (Cheli, Campagnoli, Pinotti, Fusi, & Dell'Orto, 2009; Esbensen, Paoletti, & Minkkinen, 2012; Minkkinen, Esbensen, & Paoletti, 2012). It is particularly important to determine adequate sample size within limited resources to reduce sampling error responsible for the level of uncertainty of the estimates (Hagstrum, Flinn, & Fargo, 1995; Lee et al., 2011; Minkkinen et al., 2012). The determination of sample size should be specific to a type of feed product and depends on sampling purposes and the distribution of target analyte in a feed product (Cheli et al., 2009; Minkkinen, 2004).

The sampling procedure commonly includes multiple variation sources: sampling, sample preparation, analysis (Cheli et al., 2009; Whitaker et al., 2006). The sampling phase should be the largest source of variation associated with the test procedure in feed and food products (Trucksess et al., 2009). The variability associated with the sampling phase for feed products in regulatory surveillance activities may be largely subject to the attribute of the products and the level of true attribute value of the state-wide population of feed products. Because of the variability in the sampling procedure, there is always a specific level of uncertainty about the true attribute value of the population at each phase of the sampling procedure and thus the population attribute cannot be estimated with 100% certainty in any circumstance (Whitaker et al., 2006). Whitaker, Freese, Giesbrecht, and Slate (2001) applied binomial probability distribution to show that increasing sample size reduces the variability in the mycotoxin test procedure as well as seller's/buyer's risk.

As mentioned above, application of statistical theory for sampling is a well-researched scientific area, in which the probability theory and sample distribution theory have been widely applied for selection of a proper sample size to represent the whole population (Angers, 1984; Thompson, 1987; Tortora, 1978). In this context, the Texas State Chemist developed a plan of work by applying multivariate statistical techniques to classify feed manufacturing firms based on their compliance history for product's nutritional label guarantee violation records (Lee et al., 2009). In addition to the multivariate statistical methods, the binomial probability distribution was applied in designing a new sampling protocol to develop a science-based sampling plan for better estimating chemical and biological hazards in feed products produced and distributed in the state. Further validation of the statistic model was also presented. The study represents the first and novel application of binomial probability theory for risk-based surveillance sampling design of a regulatory agency and resource optimization.

2. Materials and methods

2.1. Data collection and treatment

A sample analysis in the OTSC is carried out to determine conformance of feed products to the requirement of their label guarantee and to specific assurance level of chemical and biological hazards. In Texas, a sample that exceeds Food and Drug Administration (FDA) action levels for aflatoxins (20 μg/kg) and fumonisins (5 mg/kg) require labeling on feed products. If a sample with concentrations greater than FDA action levels shows a failure to meet a label guarantee (maximal allowable concentrations) for mycotoxin contaminants, it is considered as a protocol violation. For *Salmonella* contaminant, feed product samples indicating the presence of *Salmonella* are determined to be violative. Meanwhile, samples exceeding the levels of 2.0 ng/kg in dioxin and 0.5 mg/kg in virginiamycin are considered as a fail to meet conformance to requirements of the state regulatory authority. For the present study, data of the selected contaminants including aflatoxin, fumonisin, *Salmonella* dioxin, and virginiamycin for feed products analyzed during the 2010–2012 fiscal years were collected from the database including all records of feed product samples to prepare a data set for statistical analysis. Due to the difference in the frequency, priority, and importance of analytes and feed products during this period, the number of records used for data analysis and a sample assignment varied from analyte to analyte (Table 1).

2.2. Binomial probability theory

The probability sampling protocol designed for the assignment of chemical and biological hazard surveillance samples was drawn from the estimated confidence intervals and sample sizes at specific confidence levels under an assumption that each sample has the same probability of being selected from the state-wide population of feed products. The violation rate (p) of feed products for target analytes was computed as a ratio of the number of violative samples to the total number of samples analyzed during the 3 fiscal years. The computed violation rate serves as a key parameter of the probability statistics used for constructing a confidence interval and calculating a sample size.

In binomial probability statistics for the surveillance sampling plan, the mean (μ) and the standard deviation (σ) are defined as $\mu = np$ and $\sigma = \sqrt{np(1-p)}$, respectively, where n is the number of samples and p denotes the violation rate of samples for chemical and biological contaminants (target analytes). Three equations developed for a construction of a binomial confidence interval were employed and compared for the present study: Wald (1943) interval ($p \pm z_{\alpha/2}\sqrt{p(1-p)/n}$), Wilson (1927) interval ($\frac{p+\frac{z^2_{\alpha/2}}{2n} \pm z_{\alpha/2}\sqrt{\frac{p(1-p)}{n}+\frac{z^2_{\alpha/2}}{4n^2}}}{1+z^2_{\alpha/2}/n}$), and Agresti and Coull (1998) interval ($\tilde{p} \pm z_{\alpha/2}\sqrt{\tilde{p}(1-\tilde{p})/(n+z^2_{\alpha/2})}$), where n is a sample size, $z_{\alpha/2}$ denotes $(1-\alpha/2)100^{\text{th}}$ percentile of the standard normal distribution, and $\tilde{p}$ equals to $\frac{p+z^2_{\alpha/2}/2}{n+z^2_{\alpha/2}}$. Comparing and averaging the estimates of the confidence intervals obtained from three equations were undertaken because the equations produce different lower limits and upper-limits of confidence intervals for an identical binomial proportion (violation rate) and the difference among the estimates from different equations was quite marked, especially for a small binomial proportion. Such a confidence interval issue was in turn closely related to the estimate of a sample size for each target analyte in a specific feed product.

For the application of the binomial probability statistics to actual surveillance sampling, the widths of three confidence intervals were first averaged. The average confidence interval provides basic estimates to determine a sample size for different chemical and biological hazards in feed products. The formula used for calculating a samples size (n) is derived from the Wald interval:

$$n = \frac{z^2_{\alpha/2}p(1-p)N}{(N-1)e^2 + z^2_{\alpha/2}p(1-p)}$$

where, N: population (a total number of a specific feed product type (e.g. corn products, cottonseed, and dairy cattle feeds) produced and distributed in the state)e: acceptable error, and $z_{\alpha/2}\sqrt{\frac{p(1-p)}{\overline{n}}}$ ($\overline{n}$: an average sample size during the past 3 fiscal years)

As a result, the confidence intervals and sample sizes at different significance levels developed through the application of binomial probability statistics combined with multivariate statistical methods including principal component analysis, cluster analysis,